D7

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 39/12 // 5/14

A1

(11) International Publication Number: **WO 96/23545**

(43) International Publication Date: 8 August 1996 (08.08.96)

(21) International Application Number: PCT/FI96/00064

(22) International Filing Date: 2 February 1996 (02.02.96)

(30) Priority Data:
950468 2 February 1995 (02.02.95) FI

(71) Applicant *(for all designated States except US)*: ORION-YHTYMÄ OY [FI/FI]; Orionintie 1, FIN-02200 Espoo (FI).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: HÄMÄLÄINEN, Risto [FI/FI]; Laitilantie 11 as. 2, FIN-91600 Utajärvi (FI). NIEMI, Jukka [FI/FI]; Ratapellonkuja 2 A 4, FIN-90520 Oulu (FI). RANTALA, Mauri [FI/FI]; Kärpäntie 36, FIN-90650 Oulu (FI).

(74) Agent: ORION CORPORATION; Orion-Farmos, Research & Development, Patent Service, P.O. Box 65, FIN-20101 Espoo (FI).

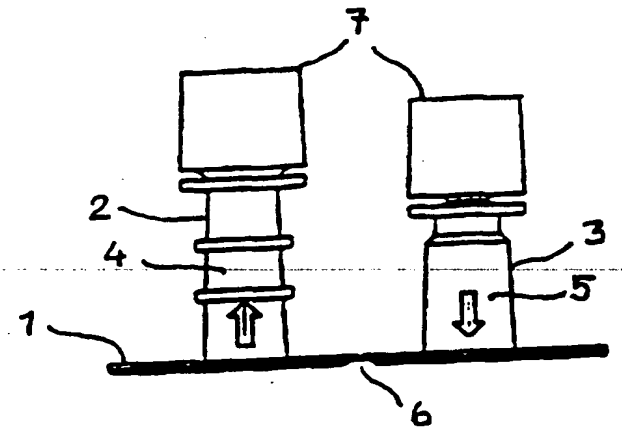
(81) Designated States: AU, BG, BR, CA, CN, CZ, EE, FI, GE, HU, JP, KG, KR, LT, LV, MK, MX, NO, NZ, PL, RO, RU, SG, SI, SK, TR, UA, US, UZ, Eurasian patent (AZ, BY, KG, KZ, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
In English translation (filed in Finnish).

(54) Title: CONNECTING ELEMENT

(57) Abstract

The invention relates to a port assembly intended for being secured to the wall membrane of an infusion fluid bag, the assembly having a base section (1) securable to the wall membrane; an administration port (2) and a medicament-adding port (3), which adjoin the base section; and a fold (4) of the base section, which divides the base section into two halves and allows the halves to fold against each other. When secured to an infusion fluid bag, the port assembly will follow the flattening shape of the emptying bag, and the bag will empty to maximal completion.



B2

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia
AT	Austria
AU	Australia
BB	Barbados
BE	Belgium
BF	Burkina Faso
BG	Bulgaria
BJ	Benin
BR	Brazil
BY	Belarus
CA	Canada
CF	Central African Republic
CG	Congo
CH	Switzerland
CI	Côte d'Ivoire
CM	Cameroon
CN	China
CS	Czechoslovakia
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
ES	Spain
FI	Finland
FR	France
GA	Gabon
GB	United Kingdom
GE	Georgia
GN	Guinea
GR	Greece
HU	Hungary
IE	Ireland
IT	Italy
JP	Japan
KE	Kenya
KG	Kyrgystan
KP	Democratic People's Republic of Korea
KR	Republic of Korea
KZ	Kazakhstan
LI	Liechtenstein
LK	Sri Lanka
LR	Liberia
LT	Lithuania
LU	Luxembourg
LV	Latvia
MC	Monaco
MD	Republic of Moldova
MG	Madagascar
ML	Mali
MN	Mongolia
MR	Mauritania
MW	Malawi
MX	Mexico
NE	Niger
NL	Netherlands
NO	Norway
NZ	New Zealand
PL	Poland
PT	Portugal
RO	Romania
RU	Russian Federation
SD	Sudan
SE	Sweden
SG	Singapore
SI	Slovenia
SK	Slovakia
SN	Senegal
SZ	Swaziland
TD	Chad
TG	Togo
TJ	Tajikistan
TT	Trinidad and Tobago
UA	Ukraine
UG	Uganda
US	United States of America
UZ	Uzbekistan
VN	Viet Nam

CONNECTING ELEMENT

The invention relates to a port assembly element suitable for an infusion fluid container. The invention relates in particular to a port assembly suitable for a plastic infusion fluid bag, through which port fluids can be withdrawn from the bag or introduced into it.

Infusion fluids such as blood, blood substitutes, dextran solutions, electrolyte solutions and various nutrient solutions are administered intravenously into a patient. Such treatment constitutes an essential part of the daily care of medical patients. In general, the fluids are administered intravenously from a dosing system in which the fluid container is suspended above the patient and the fluid flows through an administration set into the patient's vein. By an administration set is meant a tube between the fluid container and the patient, the tube being equipped with a cannula inserted into the fluid container, and often also with a drip chamber, a closing valve, and a catheter needle leading into the patient.

Often there is need to administer into a patient also medicaments such as antibiotics, cancer drugs, analgesics, etc., intravenously. In such a case it is preferable to introduce the medicaments into the infusion fluid container and mix them well with the infusion fluid, for example, by shaking the container, whereafter the dosing of the thoroughly mixed contents of the container to the patient is begun.

One advantageous package form for infusion fluid is a plastic bag. Usually there is linked to such a bag a filling tube, a withdrawing tube, and additionally a separate element intended for the adding of medicaments. In order to maintain the sterility of the contents of the infusion fluid bag it is indispensable that these throughput points for fluids have ports through which fluid can be introduced into the bag or withdrawn from it without the risk of contamination of the contents of the bag. Elements which contain one or more such ports are called below port assembly elements or more briefly port assemblies.

A number of port assemblies for infusion fluid bags have been disclosed in the patent literature. Finnish patent FI 64780 describes a package made of plastic membrane and equipped with a port assembly, for use in nursing. The package is prepared from a tubular membrane, the ends of which are closed by transverse

seams. Within the seams there are fitted two tubes, one at each end. One tube is intended as the filling tube and the other as the withdrawing tube. In the middle of the side portion of the plastic bag there is secured a separate port assembly through which the purpose is to mix in, for example, medicaments to be administered in connection with the use of an infusion fluid.

Finnish Patent FI 67482 describes a package made of plastic membrane, e.g. an infusion fluid bag, which is also a tubular membrane the ends of which are closed by transverse seams, and within which seams there are fitted two tubes in the same manner as in patent FI 64780. However, this bag is not equipped with a separate port assembly, to be placed in the middle of a side, for the adding of medicaments; this describes an assembly to be linked to either one of the tubular parts. For example, the filling tube of the bag can, after the filling, be used for forming a port assembly, thereby reducing the number of port assemblies required.

In the patent publication WO 90/06262 a port assembly has been described which comprises a base, an administration port and a medicament-adding port . The port assembly is secured to the wall membrane. This kind of port assembly has a disadvantage that the assembly can hinder the complete emptying of the bag, particularly if the port assembly is bulky.

The present invention provides a port assembly having a port for administration and a port for adding a medicament, and which assembly is meant to be secured to the membrane wall of the infusion fluid bag. The port assemby according to the invention allows the infusion fluid bag to empty to maximal completion.

The present invention relates to a port assembly intended for being secured to the wall membrane of an infusion fluid bag, the port assembly comprising a base section (1) to be secured to the wall membrane, an administration port (2) and a medicament-adding port (3), both of which adjoin the base section, and a fold (4) of the base section which divides the base section into two halves so that the administration port and the medicament-adding port each adjoins a different half of the base and which allows the halves to fold against each other.

Preferably the administration port and the medicament-adding port are at the top end protected with a closure element, such as a closure cap which can be

removed by twisting.

Preferably the medicament-adding port is equipped with a self-closing sealing piece through which an injection needle is pushed when medicaments are added into the infusion fluid container.

Preferably the fold of the base section is a groove made by thinning the base material.

According to the invention, the base section of the port assembly folds passively owing to the fold. Thus the base section becomes divided into two halves which can fold against each other.

The securing position of the port assembly to the membrane wall of the infusion fluid bag is selected so that the fold (4) and the bottom fold of the empty bag are in register. Thus, as the bag empties the halves of the port assembly turn together with the walls of the flattening bag. When the bag has completely emptied the halves are on the opposite sides of the flattened bag.

As the halves of the port assembly follow the flattening shape of the emptying bag, the bag will empty to maximal completion, since the bag walls will be able to press completely against each other without being hindered by the port assembly. This ensures that the patient will receive the intended quantity of the infusion fluid and any medicament possibly added to it. The folding halves of the base at the same time form a shield preventing the membrane material of the bag on the opposite side of the bag from being pierced when an administration cannula is inserted via the administration port or when medicaments are added by means of an injection needle via the medicament-adding port.

The port assembly according to the invention has at least two ports on the same base so that there are separate ports for the administration set and for the adding of medicaments. Thus the medicament-adding port can be used without hindrance even if the infusion fluid bag is already suspended from the rack, with the administration set linked to it. The port assembly according to the invention is secured to the outer surface of an infusion fluid bag, and thus the bag's inner surface which comes into contact with the infusion fluid will remain intact. This has a favorable effect on the stability of the infusion fluid in the bag.

An administration port according to the invention is suitable for receiving means for administering the fluid contained in the bag, via an administration set, into the patient. Such a member is most commonly the cannula of a fluid administration set.

The medicament-adding port according to the invention is suitable for receiving means for adding medicaments, usually medicament solutions, to the fluid contained in the bag. Such a member is most commonly an injection needle.

The administration port generally used in the port assembly according to the invention is preferably a cylindrical or tubular element the lower end of which adjoins the base of the port assembly, defining a channel which is in direct contact with the wall of the infusion fluid bag. The upper end of the channel of the administration port is preferably closed with a closure element by using a hermetic joint, thus ensuring the sterility of the administration port. The closure element is removed before the use of the port, and it may be any system known in the art, such as a detachable closure cap, a tear-off strip, etc. The closure element is preferably a closure cap which can be removed by twisting. The diameter of the administration port is selected so that the channel is suitable for the cannulas of commercial fluid administration sets. The fastness of the cannula in the channel of the administration port can be ensured, for example, by means of friction by making the channel slightly conical, i.e. upwardly converging, or by equipping the inner surface of the cylinder with sealing rings or friction surfaces.

The medicament-adding port used in the invention is preferably a cylindrical or tubular element the lower end of which adjoins the base section, thus defining a channel which is in direct contact with the wall of the infusion fluid bag. The upper end of the channel of the medicament-adding port is preferably closed with a closure element by using a hermetic joint, thus ensuring the sterility of the medicament-adding port. The closure element is removed before the use of the port, and it may be any system known in the art, such as a detachable closure cap, a tear-off strip, etc. The closure element is preferably a closure cap which can be removed by twisting. The channel of the medicament-adding port is additionally equipped with a self-closing sealing piece, through which an injection needle is pushed when medicaments are introduced into the infusion fluid container. Since the sealing piece of the medicament-adding port is self-closing, it prevents the

infusion fluid from leaking from the infusion fluid bag through the medicament-adding port after the injection. At the same time it prevents the access of microbes into the bag after the injection. The sealing piece is preferably made of natural rubber. The sealing piece is preferably fitted at the upper end of the channel of the medicament-adding port, in a socket which holds it mechanically in place in the channel.

The administration port and medicament-adding port used in the invention can, as is understandable, also be selected from among ports of other types known in the art. It is a prerequisite that they can be linked to the base according to the invention in such a manner that they will work in the desired manner and will not hamper the emptying of the bag.

The port assembly according to the invention is preferably made from a relatively hard plastic, preferably an elastic polypropylene or some other material homogenous with the securing region of the bag. The base section is secured to the wall membrane of the plastic infusion fluid bag preferably by ultrasound welding. For this purpose the inner surface of the base section is equipped with ridges which form an area which becomes fused to the membrane of the infusion fluid bag by ultrasound welding. The base section is preferably flat in shape. The fold of the base section can in this case be made, for example, by making in the plastic sheet a groove by thinning.

One embodiment of the invention and its functioning are described below in greater detail, with reference to Figures 1 - 4.

Figure 1 depicts the port assembly as seen from the side.
Figure 2 depicts the port assembly as seen from above.
Figure 3 is a cross-sectional representation of the port assembly, through the administration port.
Figure 4 is a cross-sectional representation of the port assembly, through the medicament-adding port.

Figure 1 shows the port assembly as seen from the side. To the flat base section (1), the lower surface of which is intended for being secured to the wall membrane of an infusion fluid bag, there adjoin an administration port (2) and a medicament-adding port (3), each of which is made up of a tubular element (4) and

(5). Also seen in the base is a thinned-out groove, which constitutes the fold (6) of the base section. The fold divides the base section into two halves which can fold against each other. The tubular elements of the administration port and the medicament-adding port end in twist-off closure caps (7), which are detached before the ports are used. Figure 2 shows the port assembly as seen from above.

Figure 3 is a cross-sectional representation of the port assembly, through the administration port. The figure shows that the lower end of the tubular element (4) of the administration port adjoins the base section (1), forming a channel (8) which is in direct contact with the wall of the infusion fluid bag. The upper end of the channel is closed with a closure cap (7) which will detach at a hermetic joint, i.e. a notch-like thinned area (9), when twisted, whereafter the cannula of an administration set can be inserted into the channel (8) for piercing the membrane of the infusion fluid bag. The channel is slightly conical, i.e. upwardly converging. In addition, the inner surface of the tubular element is equipped with a flange-like element, i.e. a sealing ring (10). This ensures that the cannula will be held in the channel by friction. The outer surface of the tubular element is equipped with three flanges, which will ensure a good finger grip at the time the cannula is being secured. The wall of the topmost portion (closest to the closure cap) of the tubular element is equipped with grooves (not visible in the figure) parallel to the longitudinal axis of the channel. These grooves will break, when necessary, if the cannula needs to be pushed deeper into the channel in order to pierce the membrane of the infusion fluid bag. The inner surface of the base section has ridges (11), which form an area which becomes fused to the membrane of the infusion fluid bag by ultrasound welding. The ridges are arranged in two pairs of rings, one ring in each half of the base section, and each ring being made up of at least two adjacent grooves, as is seen from Figure 2. The ridges (energy guides) have been designed in a manner which promotes the forming of a neat seam of a limited area between the port assembly and the bag membrane material. Thus there will not form explosively expanding air or moisture traps between the port assembly and the membrane material due to the heat of seaming during the seaming.

Figure 4 is a cross-sectional representation of the port assembly, through the medicament-adding port. The lower end of the tubular element (5) of the medicament-adding port adjoins the base section (1), defining a channel (8) which is in direct contact with the wall of the infusion fluid bag. The upper end of the

channel is closed with a closure cap (7), which will detach at a hermetic joint, i.e. a notch-like thinned area (9), when twisted. The channel is divided into a lower portion (12) and a smaller-diameter upper portion (13), the two portions being separated by a narrowing (14). A sealing piece (15) made of natural rubber is fitted in the space which is defined by the upper portion of the channel and a ringlike socket (18) adjoining the narrowing (14) and extending in the direction of the lower portion of the channel. The sealing piece is locked in place by a projection (16) on the inner surface of the socket and the narrowing (17) of the upper portion of the channel, the narrowing adjoining the notch-like thinned area. The projection (16) allows the sealing piece to be pushed into place but prevents the sealing piece from detaching from the socket. When a medicament is added, the closure cap is first detached by twisting, whereafter the needle of an injection syringe containing the medicament is inserted through the sealing piece for piercing the membrane of the infusion fluid bag. The sealing piece prevents the leakage of the infusion fluid and the access of microbes into the bag after the injection.

The base of the assembly can be prepared in a casting machine in one step as a single-part unit. The medicament-adding port and the administration port are on the same base. During transport, handling by machine, and ultrasound securing it is preferable that the welding surface of the port assembly is in its flat orientation.

Claims

1. A port assembly intended for being secured to the wall membrane of an infusion fluid bag, **characterized** in that it comprises a base section (1) securable to the wall membrane, an administration port (2) and a medicament-adding port (3), both of which adjoin the base section, and a fold (4) of the base section which divides the base section into two halves so that the administration port and the medicament-adding port each adjoins a different half of the base and which allows the halves to fold against each other.

2. A port assembly according to Claim 1, **characterized** in that when it is secured to the infusion fluid bag the fold (4) and the bottom fold of the empty bag are in register.

3. A port assembly according to Claim 1 or 2, **characterized** in that the upper ends of the administration port and the medicament-adding port are each covered by a closure element (7), preferably a closure cap which can be removed by twisting.

4. A port assembly according to any of Claims 1-3, **characterized** in that the medicament-adding port is equipped with a self-closing sealing piece (15) through which an injection needle is pushed when medicaments are introduced into the infusion fluid container.

5. A port assembly according to any of Claims 1-4, **characterized** in that the base section is flat in shape.

6. A port assembly according to any of Claims 1-5, **characterized** in that the inner surface of the base section is equipped with ridges (11) which form an area which will become fused to the membrane of the infusion fluid bag by ultrasound welding.

7. A port assembly according to any of Claims 1-6, **characterized** in that the fold of the base section is a groove made by thinning the base material.

8. A port assembly according to any of Claims 1-7, **characterized** in that the administration port is suitable for receiving means, such as the cannula of an administration set, for administering the fluid contained in the bag, via an administration set, into the patient.

9. A port assembly according to any of Claims 1-8, **characterized** in that the medicament-adding port is suitable for receiving means, such as an injection needle, for adding medicaments, usually medicament solutions, to the fluid contained in the bag.

10. A port assembly according to Claim 8, **characterized** in that the

administration port is a cylindrical or tubular element (4) the lower end of which adjoins the base section of the port assembly, defining a channel (8) which is in direct contact with the wall of the infusion fluid bag.

11. A port assembly according to Claim 4, **characterized** in that the medicament-adding port is a cylindrical or tubular element (5) the lower end of which adjoins the base section of the port assembly, defining a channel (8) which is in direct contact with the wall of the infusion fluid bag.

12. A port assembly according to Claim 10, **characterized** in that the sealing piece (15) is fitted at the upper end of the medicament-adding port, in a socket (18) which holds it mechanically in place in the channel.

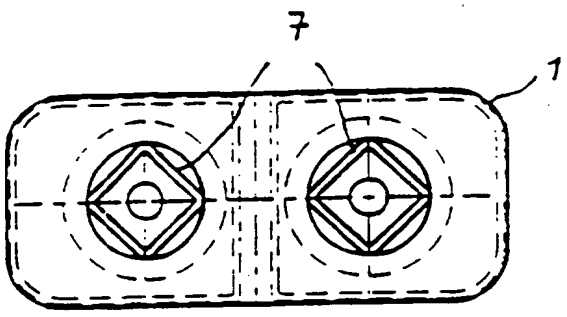


FIG. 2

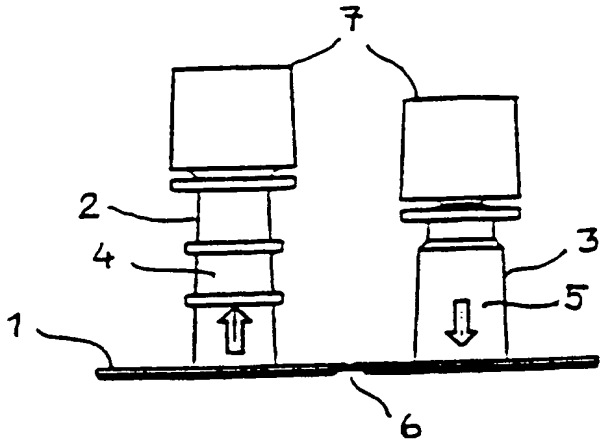


FIG. 1

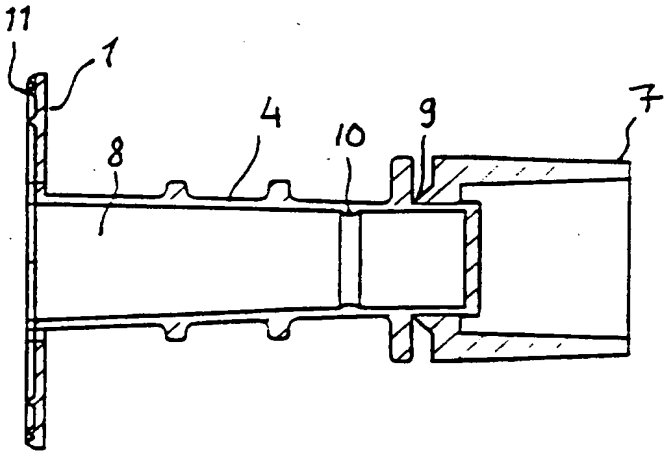


FIG. 3

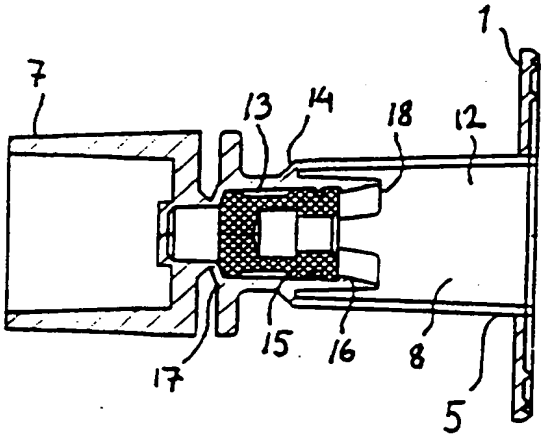


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 96/00064

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 39/12 // A61M 5/14
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DK 164487 B (A/S HAUSTRUP PLASTIC), 6 July 1992 (06.07.92) --	1,4,5,8-10, 12
A	US 2856929 A (F.C. GOSSETT ET AL), 21 October 1958 (21.10.58) --	1,4,5,8-10
A	US 3986507 A (WATT), 19 October 1976 (19.10.76) --	1-3,5,8-11
A	US 5088995 A (PACKARD ET AL), 18 February 1992 (18.02.92) --	1-5,8-12

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 May 1996	09 -05- 1996
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Leif Vingård Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 96/00064

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
A	US 5100394 A (DUDAR ET AL), 31 May 1992 (31.05.92) -- --------	1,3,4,8-12

INTERNATIONAL SEARCH REPORT

Information on patent family members

01/04/96

International application No.
PCT/FI 96/00064

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DK-B- 164487	06/07/92	NONE	
US-A- 2856929	21/10/58	NONE	
US-A- 3986507	19/10/76	NONE	
US-A- 5088995	18/02/92	AU-B- 636999	13/05/93
		AU-A- 8214391	23/01/92
		CA-A- 2064747	23/12/91
		DE-D- 69111760	00/00/00
		EP-A,A,A 0487712	03/06/92
		JP-T- 5501663	02/04/93
		WO-A,A- 9200118	09/01/92

INTERNATIONAL SEARCH REPORT

Information on patent family members

01/04/96

International application No.
PCT/FI 96/00064

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 5100394	31/05/92	AU-B- 648668	28/04/94
		AU-B- 661423	20/07/95
		AU-B- 661424	20/07/95
		AU-A- 1738592	30/07/92
		AU-A- 3039189	11/08/89
		AU-A- 5522094	23/06/94
		AU-A- 5522194	23/06/94
		CA-A- 1335167	11/04/95
		CA-A- 1337924	16/01/96
		CA-A- 1337925	16/01/96
		DE-D,T- 68916876	09/03/95
		DE-D,T- 68919861	03/08/95
		DE-D- 68924604	00/00/00
		EP-A,A,B 0354947	21/02/90
		SE-T3- 0354947	
		EP-A,A,A 0544653	02/06/93
		EP-A,A,A 0544654	02/06/93
		SE-T3- 0544654	
		EP-A,A,A 0544655	02/06/93
		SE-T3- 0544655	
		EP-A- 0659448	28/06/95
		IE-B- 62644	22/02/95
		JP-T- 2502976	20/09/90
		JP-B- 5032071	14/05/93
		US-A- 5135489	04/08/92
		US-A- 5158554	27/10/92
		US-A- 5167648	01/12/92
		US-A- 5171234	15/12/92
		US-A- 5188620	23/02/93
		US-A- 5211638	18/05/93
		US-A- 5411499	02/05/95
		WO-A,A,A 8906553	27/07/89
		AU-B- 643485	18/11/93
		AU-A- 6879791	16/05/91
		CA-A,C- 2042372	24/04/91
		DE-D,T- 69006483	15/09/94
		EP-A,A,B 0450059	09/10/91
		SE-T3- 0450059	
		EP-A,A- 0567202	27/10/93
		ES-T- 2051112	01/06/94
		JP-T- 4503179	11/06/92
		JP-B- 6026585	13/04/94
		WO-A,A- 9105581	02/05/91